

## Cell and Gene Therapy Bioanalytical Services

Supporting the CGT Development Process  
from Discovery to Market

- 100+ IND packages supported for bioanalysis with over 10 market-approved CGT therapeutics
- 20 years of regulatory experience with CGT therapeutics
- Performed under non-GLP, GLP, GMP or GCP compliance

**FDA**  
audited

**EMA**  
inspected

**NMPA**  
inspected

**IND and BLA/MAA**  
submission requirements are met

PK/TK Bioanalysis

PD & Biomarkers

Biodistribution

Viral Shedding

Immunogenicity

Cell-based Assays  
(NAb, potency)

Pharmaron is a premier R&D service provider for the life sciences industry that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.



Laboratory  
Services



Chemistry,  
Manufacturing  
& Control



Clinical  
Development



Biologics  
& CGT

# Driven by Science to Help our Partners Succeed

Discovery

Preclinical

Clinical

Market

## ► Experienced Team, State-of-the-Art Laboratories

- Study directors with 20+ years of experience in CGT bioanalysis
- Experienced with designing, developing, transferring and validating bioanalytical assays to meet regulatory guidance
- In-life facilities support non-GLP and GLP PK/biodistribution and safety/toxicity studies in small and large animals

## Drug Types & Analytes

- Viral DNA/RNA
- Plasmid DNA
- Lipids/LNPs
- Oligonucleotides
- siRNA/miRNA
- DNA & mRNA vaccines
- Gene-modified cell therapy
- Proteins & peptides
- Immunotherapy products
- Stem cell products
- Gene therapy products

## Platforms

- qPCR, dPCR, ddPCR
- Immunoassays (ELISA, hybrid ELISA, MSD<sup>®</sup>, Luminex<sup>®</sup>, Ella<sup>®</sup>)
- Western blot, fluorescence imaging (LICOR<sup>®</sup>)
- Mass spectrometry (LC-MS/MS, HRMS)
- Flow cytometry (conventional and spectral)
- Real-time cytotoxicity
- Watson-LIMS<sup>®</sup> data management

**Talk to our scientists about your drug development program today**

[bd@pharmaron.com](mailto:bd@pharmaron.com)  
[www.pharmaron.com](http://www.pharmaron.com)



康龙化成  
PHARMARON